

ABSTRACT

INTRODUCTION: Oral leukoplakia presents a long clinical course. Detection and prevention at an early stage can cause a significant reduction in the burden of treating oral cancer. Non-surgical management by indigenous plants such as Oak gall and Triphala can serve as a simple, non-toxic and culturally acceptable adjuvant in the management of Oral leukoplakia.

AIM: The aim of the study is to compare the effectiveness of Oak gall with Triphala oil as an adjuvant to tobacco cessation counselling for the reversal of oral leukoplakia.

MATERIALS AND METHODS: Subjects pre-diagnosed with oral leukoplakia (n=30) were randomized (1:1 ratio) to receive topical application of either Oak gall oil (n=15) or Triphala oil (n=15) for three months. Both the groups were given tobacco cessation counselling and multi-vitamin supplements. Clinical bidimensional measurement of the lesion was performed at baseline, sixth week and third month. Incisional punch biopsy was performed at baseline and at the end of third month. The primary outcome analysed was the clinical measurement of the lesion and histopathological response at the end of the three months. Per protocol analyses was carried. Pearson chi-square test was used to compare the proportion between the groups. Independent sample t-test was utilized to compare the means by clinical measurement between Oak gall and Triphala group. Repeated measures of ANOVA was carried out to analyse the mean reduction in size of the lesion at the three time periods.

RESULTS: A total of 21 subjects completed the trial with a clinical response rate of 45.5% in the Oak gall group and 70% in the Triphala group. Within group comparison revealed a significant reduction in the size of the lesion over the time period which is statistically significant ($p=0.003$). The difference in the clinical response between Oak gall and Triphala group was not statistically significant ($p=0.444$). Histopathological response revealed reversal of leukoplakia in 2 subjects in the Oak gall and 2 subjects in the Triphala group.

CONCLUSION: Indigenous plant products such as Oak gall and Triphala oil can be used as an adjuvant in the management of oral leukoplakia. Long term clinical trials with well-defined end points such as biomarkers for the measurement of reversal of lesion is a definite need of the hour.

DENTAL PUBLIC HEALTH SIGNIFICANCE: Indigenous plant products such as Oak gall and Triphala oil can serve as simple, safe, culturally acceptable adjuvant in the management of oral leukoplakia and thus can prevent malignant transformation thereby reducing the economic burden of treating oral cancer.

KEY WORDS: Oak gall oil, Triphala oil, oral leukoplakia, clinical trial